REMARKS

In response to the Office Action dated January 21, 2004, the time for response having been extended by petition, Applicant submits the following remarks. Claims 47-60, 63 and 68-70 remain in this application. Claims 68-70 are new, submitted to further define the invention, and do not add any new matter.

The Examiner rejected claims 47-60 and 63 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 60 to more clearly define the invention. Regarding claims 47-48, Figure 1B and the specification at page 11, lines 1-17, provides support for the claims as written. As is claimed in claim 68, the tubular member becomes fluent upon application of energy, as such prior to the application of energy, the tubular member may be pre-shaped or bent. Applicant requests that the Examiner withdraw the rejection.

The Examiner rejected claims 49-55 and 58-60 under 35 USC §102(e) as being anticipated by Slepian (US Patent No. 5,634,946). Applicant traverses this rejection. The Examiner states that "Slepian shows a fastener" and cites three locations in Slepian for support of that proposition. Applicant has reviewed Slepian in detail and can not locate any support for the proposition that Slepian shows a fastener.

Slepian describes a polymer for use to coat, pave or seal, among other surfaces, the interior of a blood vessel. The polymer is described as being particularly useful "as an alternative to conventional stenting techniques as well as a method for providing biocompatible polymeric materials in vivo." Slepian, Summary, col 4, lines 55-57. In addition, Slepian describes other uses for the polymer:

> Although having particular advantages for preventing restenosis in coronary blood vessels following angioplasty, the PEPS approach is not limited to use in connection with restenosis. The procedure can also be effectively employed in any tubular or hollow organ to provide local structural support, smooth surface characteristics, improved flow, barrier placement or imposition, and sealing of lesions. In addition, the polymeric paving and sealing material may incorporate therapeutic agents such as drugs, drug producing cells, cell inhibition and/or regeneration factors or

> even progenitor cells of the same type as the involved organ or a histologically different organ to accelerate and/or inhibit or retard healing processes. Materials with incorporated therapeutic agents may be effectively used to coat or plug hollow spaces or lumens formed by surgery, trauma or disease in normally solid organs as well as to coat or plug hollow spaces or lumens formed by surgery, percutaneous techniques, trauma or disease in normally hollow or tubular organs.

Col 5, lines 21-40. Nowhere does Slepian describe using the polymer as a "fastener for sealingly joining a graft lumen to a target vessel in an anastomosis", as is claimed in claim 60.

At page 3 of the Office Action, the Examiner recites three locations within Slepian as support for the proposition that Slepian shows a fastener. None of these locations describes using the polymer as a connector. The first location referred to by the Examiner is at column 10, line 46 through column 11, line 5, where Slepian describes a sleeve that may be "readily insertable along with the catheter into the tissue lumen, and then to be deployed onto the wall of the lumen to form the coating." Col 10, lines 46-50. A balloon catheter can be used to expand the sleeve "causing it [to] press against the walls of the tissue lumen and acquire the shape corresponding to the lumen wall." Col 10, lines 55-57. This location refers to using the polymer in place of a stent to coat the wall of a lumen.

The next location referred to by the Examiner is column 12, lines 9-12, which are as follows: "Further, PEPS provides intraoperative uses such as ***sealing of vessel anastomoses*** during coronary artery bypass grafting and the ability to provide a "bandaged" smooth polymer surface." This reference describes "sealing of vessel anastomoses", as opposed to creating a vessel anastomosis. It appears that Slepian suggests ***sealing*** vessel anastomoses that had already been created during coronary artery bypass grafting. Such a use, Slepian suggests, would provide a "bandaged" smooth polymer surface.

Such sealing is entirely consistent with the remainder of the Slepian specification and does not suggest the fastener of claim 60: a fastener that includes a tubular member formed of a deformable material that is sized and dimensioned for receiving an end portion of said graft lumen, wherein the tubular member is radially expandable upon application of energy to the tubular member to permit radial expansion of the graft lumen to an expanded state, whereat

the tubular member retains the end portion of the graft lumen in its expanded state in sealing engagement with the target vessel.

Turning to the third reference, column 13, lines 13-16 of Slepian read as follows: "Complex internal applications of thicker layers of polymer, such as intravessel or intra-luminal applications can provide increased structural support, and can serve a mechanical role to maintain vessel or organ patency." Again, this excerpt does not describe a fastener; it simply states that the use of the polymer as described elsewhere in Slepian can provide "increased structural support", and can help to maintain vessel patency. Such benefits are consistent with using the polymer as a replacement for a stent, and do not suggest that the polymer can be used as a fastener.

Because Slepian does not teach or suggest the fastener claimed in claim 60, Applicant submits that the 102 rejection should be withdrawn as to the independent claim 60, and the claims that depend therefrom.

The Examiner further rejects claims 47-48, 56-57 and 63 under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Nash (6056762), Pathak (5,662,712) and Hubbell (5,410,016). Each of these rejections relies upon Slepian as the primary reference, which as described above fails to teach or suggest the elements of the independent claim, claim 60. As a result, the combination of Nash or Pathak or Hubbell with Slepian fails to teach or suggest the elements of the independent claim, or the dependent claims 47-59, 63, and 68-70, respectively.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case, and request the Examiner to contact the undersigned representative in the event that a conference would clarify any remaining issues.

Respectfully submitted,

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